



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0902]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Product Labeling: Medication Guide Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0393. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Juanmanuel Vilela,

Office of Information Management,

Food and Drug Administration,

1350 Piccard Dr.,

PI50-400B,

Rockville, MD 20850,

301-796-7651,

juanmanuel.vilela@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug Product Labeling; Medication Guide Requirements (OMB Control Number 0910-0393)--Extension

FDA regulations require the distribution of patient labeling, called Medication Guides, for certain prescription human drug and biological products used primarily on an outpatient basis that pose a serious and significant public health concern requiring distribution of FDA-approved patient medication information. These Medication Guides inform patients about the most important information they should know about these products in order to use them safely and effectively. Included is information such as the drug's approved uses, contraindications, adverse drug reactions, and cautions for specific populations, with a focus on why the particular product requires a Medication Guide. These regulations are intended to improve the public health by providing information necessary for patients to use certain medication safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA. The estimates for the burden hours imposed by the following regulations are listed in table 1 of this document:

- 21 CFR 208.20--Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.

- 21 CFR 208.24(e)--Each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient's agent, must provide a Medication Guide directly to each patient unless an exemption applies under 21 CFR 208.26.

- 21 CFR 208.26 (a)--Requests may be submitted for exemption or deferral from particular Medication Guide content or format requirements.

- 21 CFR 314.70(b)(3)(ii) and 21 CFR 601.12(f)--Application holders must submit changes to Medication Guides to FDA for prior approval as supplements to their applications.

In the Federal Register of December 21, 2011 (76 FR 79194), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received the following comments:

(Comment 1) One comment states that FDA's hourly burden estimate of 3 minutes per Medication Guide for pharmacists to comply with the requirements is miscalculated, although more in line with current practices versus previous FDA estimates.

(Response) Because the comment did not indicate if the miscalculation was over-or under-estimated or provide alternative burden estimates for pharmacy time associated with distribution of a Medication Guide, we continue to use 3 minutes as the estimated burden for pharmacists to distribute Medication Guides to patients.

(Comment 2) One comment said that there are distributor costs to comply with the Medication Guide requirements and FDA's estimate omits § 208.24(c), which provides that "Each distributor or packer that receives Medication Guides, or the means to produce Medication

Guides, from a manufacturer under paragraph (b) of this section shall provide those Medication Guides, or the means to produce Medication Guides, to each authorized dispenser to whom it ships a container of drug product.” The comment states that the December 21, 2011, notice of proposed information collection (76 FR 79194) does not include an estimate for the reporting requirements of § 208.24(c) and that the requirement should be included in FDA’s assessment.

(Response) FDA has re-evaluated § 208.24(c) with regards to information collection burden on distributors and packers and determined that § 208.24(c) does not contain an additional collection of information subject to the reporting requirements of the PRA. A “collection of information” includes an Agency request or requirement that members of the public submit reports, keep records, or provide information to third parties or the public by or for an Agency. Therefore, the manufacturer is responsible for providing information to third parties (§ 208.24(a)), i.e., Medication Guides, and the distributor or packer distributes the Medication Guides with the shipment of drugs to the dispensers. Thus, § 208.24(c) is not subject to the reporting requirements of the PRA.

(Comment 3) One comment says that FDA should reassess the need to provide Medication Guides with each prescription refill and states there are situations where it is not necessary due to certain circumstances. The comment states that Medication Guides should be a tool to enhance the level of care to consumers, rather than a hindrance to pharmacists in their ability to provide quality patient care.

(Response) FDA agrees and directs the comment to the guidance made available to the public entitled “Medication Guides–Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS).” In this guidance, FDA articulates the circumstances under

which FDA intends to exercise enforcement discretion regarding the requirement to provide Medication Guides in certain settings.

(Comment 4) One comment states that Medication Guides increasingly become accessible online for download and print and the costs for printing, including paper, toner, administrative, and software costs, have shifted from the manufacturers to the pharmacies.

(Response) While Medication Guides are increasingly available online for download and printing, the FDA does not agree that a financial and acquisition burden has shifted to or been created for dispensers. The comment mischaracterizes the cost to dispensers associated with the distribution of Medication Guides. For purposes of information collection requests under the PRA, capital costs are costs for equipment, machinery, and construction that, if not for FDA's request or requirement, the respondent would not incur. Capital costs do not include costs to achieve regulatory compliance. The costs presented by the comment are not capital costs because they are costs associated with achieving regulatory compliance with requirements of the FD&C Act, not costs associated specifically with equipment, machinery, and construction needed to retain appropriate substantiating evidence.

(Comment 5) One comment states that the length of Medication Guides continues to be burdensome and hinders a pharmacist from utilizing a potentially effective tool. The comment stresses the need for a succinct, one-page document that can be easily integrated into current pharmacy practice workflow.

(Response) FDA generally agrees with the comment and is currently in the process of evaluating whether a one-page solution can be implemented.

FDA estimates the burden of this collection of information as follows:

Table 1--Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
208.20	25	1	25	320	8,000
314.70(b)(3)(ii), 601.12(f)	5	1	5	72	360
208.24(e)	59,000	5,000	295 million	3 minutes	14,750,000
208.26(a)	1	1	1	4	4
Total					14,758,364

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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